2. The method according to claim 1, in which the] The promoter [is] can be an inducible promoter.[

3. The method according to claim 2, in which the] The inducible promoter [is] can be induced by mechanical gene activation.[

4.] The method [according to claim 2, which is] can be carried out with the transgenic plant and additionally comprises a step of inducing the inducible promoter before or after the transgenic plant is harvested, which inducing step is carried out before recovering the lysosomal enzyme from the cell, tissue or organ of the transgenic plant.[

5. The method according to claim 1, in which the] The lysosomal enzyme [is] can be a modified lysosomal enzyme which is enzymatically active and comprises: [

](a) an enzymatically-active fragment of a human or animal lysosomal enzyme; [

](b) the human or animal lysosomal enzyme or (a) having one or more amino acid residues added to the amino or carboxyl terminus of the human or animal lysosomal enzyme or (a); or[

](c) the human or animal lysosomal enzyme or (a) having one or more naturally-occurring amino acid additions, deletions or substitutions. [

6. The method according to claim 5, in which the] The modified lysosomal enzyme [comprises] can comprise a signal peptide or detectable marker peptide at the amino or carboxyl terminal of the modified lysosomal enzyme. [

7. The method according to claim 6, in which the] The modified lysosomal enzyme [is] can be recovered from (i) the transgenic plant cell or (ii) the cell, tissue or organ of the transgenic plant by reacting with an antibody that binds the detectable marker peptide. [

8. The method according to claim 7, in which the] The antibody [is] can be a monoclonal antibody. [

9. The method according to claim 5, in which the] The modified lysosomal enzyme [comprises] can comprise : [

](a) an enzymatically-active fragment of an *a*.-N-acetylgalactosaminidise, acid lipase, *a*-galactosidase, glucocerebrosidase, *a*.-L-iduronidase, iduronak sulfatase, *a*-mannosidase or sialidase; [

](b) the *a*-N-acetylgalactosaminidase, acid lipase, *a*-galactosidase, glucocerebrosidase, *a*-L-iduronidase, iduronate sulfatase, *a*-mannosidase, sialidase or (a) having one or more amino acid residues added to the amino or carboxyl terminus of the *a*-N-acetylgalactosaminidase, acid lipase, *a*-galactosidase, glucocerebrosidase, *a*-L-iduronidase, iduronate sulfatase, *a* -mannosidase, sialidase or (a); or [

](c) the *a*-N-acetylgalactosaminidase, acid lipase, *a*-galactosidase, glucocerebrosidase, *a*-L-iduronidase, iduronate sulfatase, *a*-mannosidase, sialidasc or (a) having one or more naturally-occurring amino acid additions, deletions or substitutions. [

10. The method according to claim 9, in which the] The modified lysosomal enzyme [comprises] can comprise : [

](a) an enzymatically-active fragment of a human glucocerebrosidase or human α-L-iduronidase enzyme; [

](b) the human glucocerebrosidase, human α-L-iduronidase or (a) having one or more amino acid residues added to the amino or carboxyl terminus of the human glucocerebrosidase, human α-L-iduronidase or (a); or [

](c) the human glucocerebrosidase, human α-L-iduronidase or (a) having one or more naturally-occurring amino acid additions, deletions or substitutions. [

11. The method according to claim 5, in which the] The modified lysosomal enzyme [is] can be a fusion protein comprising: [

](I) (a) the enzymatically-active fragment of the human or animal lysosomal enzyme, [

](b) the human or animal lysosomal enzyme, or [

](c) the human or animal lysosomal enzyme or (a) having one or more naturally-occurring amino acid additions, deletions or substitutions, and [

](II) a cleavable linker fused to the amino or carboxyl terminus of (I); and the method comprises: [

](a) recovering the fusion protein from the transgenic plant cell, or the cell, tissue or organ of the transgenic plant; [

](b) treating the fusion protein with a substance that cleaves the cleavable linker so that (I)is separated from the cleavable linker and any sequence attached thereto; and [

](c) recovering the separated (I). [

12. The method according to claim 1, in which the] The transgenic plant [is] can be a transgenic tobacco plant. [

13. The method according to claim 1, in which the] The lysosomal enzyme [is] can be a human or animal lysosomal enzyme. [

14. The method according to claim 13, in which the] The lysosomal enzyme [is] can be an α-N-acetylgalactosaminidase, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfatase, α-mannosidase or sialidese. [

15. The method according to claim 14, in which the] The lysosomal enzyme [is] can be a human glucocerebrosidase or human α-L-iduronidase. [

16. The method according to claim 1, in which the] The organ [is] can be a leaf, stem, root, flower, fruit or seed.

[17. A] The present invention provides for a recombinant expression construct comprising a nucleotide sequence encoding a protein of choice comprising a lysosomal enzyme and a promoter that regulates the expression of the nucleotide sequence in a plant cell. [

18. The recombinant expression construct of claim 17, in which the] The promoter [is] can be an inducible promoter. [

19. The recombinant expression construct of claim 18, in which the] The inducible promoter [is] can be induced by mechanical gene activation. [

20. The recombinant expression construct of claim 17, in which the] The lysosomal enzyme [is] can be a modified lysosomal enzyme which is enzymatically active and comprises: [

](a) an enzymatically-active fragment of a human or animal lysosomal enzyme; [

](b) the human or animal lysosomal enzyme or (a) having one or more amino acid residues added to the amino or carboxyl terminus of the human or animal lysosomal enzyme or (a); or [

](c) the human or animal lysosomal enzyme or (a) having one or more naturally-occurring

21. The recombinant expression construct of claim 20, in which the] The modified lysosomal enzyme [comprises] can comprise a signal peptide or detectable marker peptide at the amino or carboxyl terminal of the modified lysosomal enzyme. [

22. The recombinant expression construct of claim 21, in which the] The detectable marker peptide 15 [comprises] can comprise SEQ ID NO: 10. [

23. The recombinant expression construct of claim 20, in which the] The modified lysosomal enzyme [comprises:

] can comprise (a) an enzymatically-active fragment of an α-N-acetylgalactosaminidase, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfatase, α-mannosidase or sialidase; [

](b) the α-N-acetylgalactosaminidase, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfatase, α-mannosidase, sialidase or (a) having one or more amino acid residues added to the amino or carboxyl terminus of the α-N-acetylgalactosaminidase, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfatase, α-mannosidase, sialidase or (a); or [

](c) the α-N-acetylgalactosaminidase, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfatase, α-mannosidase, sialidase or (a) having one or more naturally-occurring amino acid additions, deletions or substitutions. [

24. The recombinant expression construct of claim 23, in which the] The modified lysosomal enzyme [comprises:

] can comprise (a) an enzymatically-active fragment of a human glucocerebrosidase or human

](b) the human glucocerebrosidase or human α-L-iduronidase or (a) having one or more amino acid residues added to the amino or carboxyl terminus of the human glucocerebrosidase, human α-L-iduronidase or (a); or [

](c) the human glucocerebrosidase, human α-L-iduronidase or (a) having one or more naturally-occurring amino acid additions, deletions or substitutions. [

25. The expression construct of claim 20, in which the] The modified lysosomal enzyme [is] can be a fusion protein comprising [

] can comprise: (I) (a) the enzymatically-active fragment of the human or animal lysosomal enzyme, [

](b) the human or animal lysosomal enzyme, or [

](c) the human or animal lysosomal enzyme or (a) having one or more naturally-occurring amino acid additions, deletions or substitutions, and [

](II) a cleavable linker fused to the amino or carboxyl terminus of (I). [

26. The recombinant expression construct of claim 17, in which the] The lysosomal enzyme [is] can be a human or animal lysosomal enzyme. [

27. The recombinant expression construct of claim 25, in which the] The lysosomal enzyme [is] can be an α-N-acetylgalactosaminidase, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfatase, α-mannosidase or sialidase. [

28. The recombinant expression construct of claim 27, in which the] The lysosomal enzyme

29. A] The present invention provides for a plant transformation vector comprising any of the recombinant expression construct [of claim 17, 18, 20, 21, 24, 25, or 28] recited above . [

30. A] The present invention provides for a plant which is transformed or transfected with any of the recombinant expression construct [of claim 17, 18, 20, 21, 24, 25, or 28] recited above . [

31. A] The present invention provides for a plant cell, tissue or organ which is transformed or transfected with any of the recombinant expression construct [of claim 17, 18, 20, 21, 24, 25, or 28] recited above . [

32. A] The present invention provides for a plant transfection vector comprising any of the recombinant expression construct [of claim 17, 18, 20, 21, 24, 25, or 28] recited above . [

33. A] The present invention provides for a plasmid comprising any of the recombinant expression construct [of claim 17, 18, 20, 21, 24, 25, or 28] recited above . [

34. A] The present invention provides for a transgenic plant or plant cell capable of producing a lysosomal enzyme which is enzymatically active, which transgenic plant or plant cell is transformed or transfected with a recombinant expression construct comprising a nucleotide sequence encoding a lysosomal enzyme and a promoter that regulates expression of the nucleotide sequence in the transgenic plant or plant cell. [

35. The transgenic plant or plant cell of claim 34, in which the] The promoter is an inducible promoter. [

36. The transgenic plant or plant cell of claim 35, in which the] The inducible promoter is

37. The transgenic plant or plant cell of claim 36, in which the] The inducible promoter comprises SEQ ID NO: 5. [

38. The transgenic plant or plant cell of claim 34, in which the] The lysosomal enzyme which is a modified lysosomal enzyme which is enzymatically active and which comprises: [

](a) an enzymatically-active fragment of a human or animal lysosomal enzyme; [

](b) the human or animal lysosomal enzyme or (a) having one or more amino acid residues added to the amino or carboxyl terminus of the human or animal lysosomal enzyme or (a); or [

](c) the human or animal lysosomal enzyme or (a) having one or more naturally-occurring amino acid additions, deletions or substitutions. [

39. The transgenic plant or plant cell of claim 38, in which the] The modified lysosomal enzyme comprises a signal peptide or detectable marker peptide at the amino or carboxyl terminal of the modified lysosomal enzyme. [

40. The transgenic plant or plant cell of claim 39, in which the] The detectable marker peptide comprises SEQ ID NO: 10. [

41. The transgenic plant or plant cell of claim 38, in which the] The modified lysosomal enzyme comprises: [

](a) an enzymatically-active fragment of an α-N-acetylgalactosaminidase, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfatase, α-mannosidase or sialidase; [

iduronidase, iduronate sulfatase, α-mannosidase, sialidase or (a) having one or more amino acid residues added to the amino or carboxyl terminus of the α-N-acetylgalactosaminidase, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfatase, amannosidase, sialidase or (a); or [

](c) the α-N-acetylgalactosaminidase, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfatase, α-mannosidase, sialidase or (a) having one or more naturally-occurring amino acid additions, deletions or substitutions. [

42. The transgenic plant or plant cell of claim 41, in which the] The modified lysosomal enzyme comprises: [

](a) an enzymatically-active fragment of a human glucocerebrosidase or human α-L-iduronidase enzyme; [

](b) the human glucocerebrosidase, human α-L-iduronidase or (a) having one or more amino acid residues added to the amino or carboxyl terminus of the human glucocerebrosidase, human α-L-iduronidase or (a); or [

](c) the human glucocerebrosidase, human *a*-L-iduronidase or (a) having one or more naturally-occurring amino acid additions, deletions or substitutions. [

43. The transgenic plant or plant cell of claim 38, in which the] The modified lysosomal enzyme is a fusion protein comprising: [

](1) (a) the enzymatically-active fragment of the human or animal lysosomal enzyme, [

](b) the human or animal lysosomal enzyme, or [

amino acid additions, deletions or substitutions, and [

](II) a cleavable linker fused to the amino or carboxyl terminus of (I). [

44. The transgenic plant or plant cell of claim 34, in which the] The transgenic plant or plant cell is a transgenic tobacco plant or tobacco cell. [

45. The transgenic plant or plant cell of claim 34, in which the] The lysosomal enzyme is a human or animal lysosomal enzyme. [

46. The transgenic plant or plant cell of claim 45, in which the] The lysosomal enzyme is an *a*-N-acetylgalactosaminidase, acid lipase, *a*-galactosidase, glucocerebrosidase, *a*-L-iduronidase, iduronate sulfatase, *a*-mannosidase or sialidase. [

47. The transgenic plant or plant cell of claim 46, in which the] The lysosomal enzyme is a human glucocerebrosidase or human *a*-L-iduronidase. [

48. A] The present invention provides for a leaf, stem, root, flower or seed of any of the transgenic plant [of claim 34, 35, 38, 39, 42, 44, 45, or 47] recited above . [

49. A] The present invention provides for a seed of plant line Nicotiana sp., which seed has the ATCC Accession No. -------, deposited July 25, 2000. [

50. A] The present invention provides for a plant grown from the seed [of claim 49] recited above . [

51. A] The present invention provides for a lysosomal enzyme which is enzymatically active and is produced according to a process comprising: [

of a transgenic plant which transgenic plant cell or plant is transformed or transfected with a recombinant expression construct comprising a nucleotide sequence encoding the lysosomal enzyme and a promoter that regulates expression of the nucleotide sequence so that the lysosomal enzyme is expressed by the transgenic plant cell or plant. [

52. The lysosomal enzyme of claim 59, in which the] The promoter [is] can be an inducible promoter.[

53. The lysosomal enzyme of claim 52, which] The process is carried out with the transgenic plant and additionally [comprises] can comprise a step of inducing the inducible promoter before or after the transgenic plant is harvested, which inducing step is carried out before recovering the lysosomal enzyme from the cell, tissue or organ of the transgenic plant. [

54. The lysosomal enzyme of claim 51, which is a] The modified lysosomal enzyme which [is] can be enzymatically active and [comprises:

] can comprise: (a) an enzymatically-active fragment of a human or animal lysosomal enzyme; [

](b) the human or animal lysosomal enzyme or (a) having one or more amino acid residues added to the amino or carboxyl terminus of the human or animal lysosomal enzyme or (a); or[

](c) the human or animal lysosomal enzyme or (a) having one or more naturally-occurring amino acid, additions, deletions or substitutions. [

55. The lysosomal enzyme of claim 54, in which the] The modified lysosomal enzyme [comprises] can comprise a signal peptide or detectable marker peptide at the amino or carboxyl terminal of the modified lysosomal enzyme. [

56. The lysosomal enzyme of claim 54, in which the] The modified lysosomal enzyme [comprises:

] can comprise: (a) an enzymatically-active fragment of an α-N-acetylgalactosaminidase, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfatase, α-mannosidase or sialidase; [

](b) the α-N-acetylgalactosaminidase, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfatase, α-mannosidase, sialidase or (a) having one or more amino acid residues added to the amino or carboxyl terminus of the α-N-acetylgalactosaminidase, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfatase, amannosidase, sialidase or (a); or [

](c) the α-N-acetylgalactosaminidasd, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfazase, α-mannosidase, sialidase or (a) having one or more naturally-occurring amino acid additions, deletions or substitutions. [

57. The lysosomal enzyme of claim 56, in which the] The modified lysosomal enzyme comprises: [

](a) an enzymatically-active fragment of a human glucocerebrosidase or human α-L-iduronidase enzyme; [

](b) the human glucocerebrosidase, human α-L-iduronidase or (a) having one or more amino acid residues added to the amino or carboxyl terminus of the human glucocerebrosidase, human α-L-iduronidase or (a); or [

](c) the human glucocerebrosidase, human α-L-iduronidase or (a) having one or more naturally-occurring amino acid additions, deletions or substitutions. [

can be a fusion protein comprising: [

](I) (a) the enzymatically-active fragment of the human or animal lysosomal enzyme, [

](b) the human or animal lysosomal enzyme, or [

](c) the human or animal lysosomal enzyme or (a) having one or more naturally-occurring amino acid additions, deletions or substitutions, and [

](II) a cleavable linker fused to the amino or carboxyl terminus of (I). [

59. The lysosomal enzyme of claim 51, in which the] The transgenic plant [is] can be a transgenic tobacco plant. [

60. The lysosomal enzyme of claim 51, in which the] The lysosomal enzyme [is] can be a human or animal lysosomal enzyme. [

61. The lysosomal enzyme of claim 60, in which the] The lysosomal enzyme [is] can be an α-N-acetylgalactosaminidase, acid lipase, α-galactosidase, glucocerebrosidase, α-L-iduronidase, iduronate sulfatase, α-mannosidase or sialidase. [

62. The lysosomal enzyme of claim 61, in which the] The lysosomal enzyme [is] can be a human glucocerebrosidase or human α-L-iduronidase. [

63. The lysosomal enzyme of claim 51, in which the] The organ [is] can be a leaf, stem, root, flower, fruit or seed."

## THE REMARKS